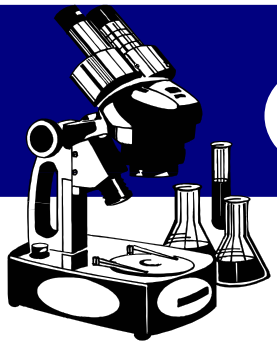


CLIA BITS

North Dakota Department of Health
Division of Health Facilities
Spring 2003

Clinical Laboratory Improvement Amendments (CLIA)

Finally, a "final" "final" publication to streamline and simplify quality and personnel rules for clinical laboratories. The new rules are designed to enhance patient safety while making it easier for laboratories to understand and comply with these requirements. The changes are part of a broader effort across the U.S. Department of Health and Human Services to restore common sense to the regulatory process and promote higher quality of care.

The major items affected by the new regulation are listed in the tables to follow. Additionally, the new regulation clarifies, simplifies and reorganizes the existing requirements to parallel the flow of a patient specimen through the laboratory. This reorganization should help laboratories understand and apply the requirements more easily and reduce lab errors. The final rule reduces the frequency with which laboratories must perform quality control (QC) in most specialty and subspecialty areas and brings all non-waived testing under the same QC requirements. Personnel standards will continue to be based on test complexity.

Based on Clinical Laboratory Improvement Advisory Committee (CLIAC) recommendations and Centers for Medicare and Medicaid Services (CMS) survey data, the rules now require laboratories to validate the accuracy of moderate as well as high complexity tests prior to the testing of patient specimens and the reporting of those results; however, requirements for routine QC will be more flexible. Guidelines will be developed for laboratories to use to meet the federal requirements and will be posted on the CMS website when available.

The final rule also grandfathers certain non-board certified individuals with a doctoral degree who have served, or are currently serving, as a director of a laboratory performing high complexity testing, allowing them to continue directing high complexity laboratories despite their lack of board certification. All new directors of high complexity laboratories who have a doctorate, rather than a medical degree, will need to be board certified.

The regulation was published Jan. 24, 2003 and had a 90-day effective date. The effective date for the final CLIA rules was April 24, 2003.

Compared to the 1992 regulation, the impact statement demonstrates an overall decrease in costs to laboratories to comply with the changes in the regulation.

More information is available at:

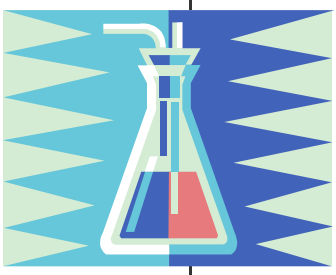
www.health.state.nd.us/hf/North_Dakota_clinical_laboratories.htm

Inside this issue:

Special points of interest:

- Examine the comparison between current and new regulations.
- See how the new regulations will impact your laboratory.
- Compare the existing and new regulations in microbiology, hematology, immunology and serology

Changes from Current Regulation (HCFA-176FC) (CMS-2226F)

Current	Changes	Impact	Rationale
1. Quality Control (QC) frequency	Reduces most specialty and subspecialty QC frequency.	Reduces costs and workload due to less frequent QC monitoring.	• New technology allows the laboratory to customize their QC program based on the testing personnel's expertise and the technology of the device.
2. QC phase-in for moderate complexity tests includes limited requirements. 	Concludes the QC phase-in. There will be one set of QC standards for moderate and high complexity testing.	Will require laboratories performing moderate complexity tests to perform validation for each new test. Laboratories may perceive this as a burden. Laboratories will have more flexibility to meet QC requirements.	• Technological advances in test systems. • Education and training of personnel. • Competency evaluations. • More than 944 moderate complexity test systems have been waived since 1992. Remaining moderate tests are more complex to perform. • Survey data (covering ten years) shows the need for quality review. • The CLIAC recommended validating test systems and most accredited organizations currently require this QC validation. • Manufacturers currently assist laboratories with QC validation.
3. Board certification phase-in of doctoral degree laboratory directors of high complexity testing.	Concludes the phase-in, "grandfathering" current doctoral degree laboratory directors (with experience) without board certification.	Individuals with a doctoral degree directing laboratories of high complexity testing must be board certified after the effective date of the regulation. This finalizes CMS-2094P.	• CLIAC recommended board certification for laboratory directors. • The comments emphasize the role of board certification in ensuring individuals have clinical knowledge, skills and competencies. • The number of approved boards was expanded during the phase-in.
4. FDA review of test systems as meeting certain CLIA QC requirements.	Removes the required FDA review that was to occur after the end of the QC phase-in.	Manufacturers in favor of FDA review. No expectation from laboratories. OMB previously requested that this remain as a future requirement.	• The FDA review is no longer required and is a redundant process. • Manufacturers cannot cover all QC requirements since many are unique to each laboratory. CMS must survey for QC compliance. • FDA review is process oriented, CMS review is outcome oriented. • CLIA cannot afford to fund review of 15,000 test systems without significant increases.
5. Federal, State and Local Laws (not currently included).	Requires adherence to other Federal, State and Local Laws.	Federal programs facilitate State removal of licensure.	• Department removed from current rule. CLIA may refer findings to other agencies, but doesn't review problems outside of CLIA.

Changes from Current Regulation (HCFA-176FC) (CMS-2226F) (cont)

Current	Changes	Impact	Rationale
6. The requirements for existing subparts J-Patient Test Management (record keeping), K-Quality Control and P-Quality Assurance.	Existing subparts J, K and P combined into two new subparts: J-Facility Administration and K-Quality Systems.	Regulatory requirements follow the route of a specimen through the laboratory; i.e. the specimen receiving, testing and reporting. May facilitate prevention of laboratory errors.	• Clarifies requirements, includes plain language, reduces redundancy and is easier to follow. • A CLIAC recommendation that makes CLIA Quality Systems oriented.
7. Total cost of current rule.	Overall impact decreases cost.	Positive	• Technological improvement. • Data demonstrates allowable reductions.

If your laboratory would like to receive *CLIA Bits* electronically, please send your e-mail address to bweidner@state.nd.us.

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www.health.state.nd.us

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Changes to Microbiology, Hematology, Immunology and Serology Requirements

Existing Regulations	New Regulations (Published Jan. 24, 2003) (68 FR 3640)
Bacteriology	
Each day of use, check catalase, coagulase, beta-lactamase, and oxidase reagents and DNA probes using a positive and negative control. Each week of use check bacitracin, optochin, ONPG, X, and V discs or strips using a positive and negative control.	(NC) Each day of use, check beta-lactamase (other than cefinase (D)) and DNA probes using a positive and negative control. (D) Check each batch, lot number and shipment of reagents (catalase, coagulase and oxidase), disks (bacitracin, optochin, ONPG, X, V and XV), stains, antisera and identification systems for positive and negative reactivity, and graded reactivity if applicable.
Each month of use check antisera using a positive and negative control.	(D) Check each batch, lot number and shipment of antisera when prepared or opened and once every six months thereafter using a positive and negative control.
Mycobacteriology	
Each day of use, check iron uptake test using a positive and negative acid-fast organism and check all other reagents or test procedures using a positive acid-fast organism.	(I) Each day of use, check all mycobacteriology reagents ((NC) iron uptake test) using a positive and negative acid-fast organism.
Each week of use check acid-fast stains using a positive control.	(I) Each day of use, check acid fast stains using a positive and negative control.
Each week of use, check fluorochrome acid-fast stains using positive and negative controls.	(I) Each time of use, check fluorochrome stains using positive and negative controls.
Mycology	
Each day of use, test staining materials (lactophenol cotton blue) for intended reactivity. Each week of use, check biochemical tests and mycological identification tests (germ tube) with a positive control.	(D) Check each batch, lot number and shipment of lactophenol cotton blue when prepared or opened for intended reactivity. (D) Check each batch, lot number and shipment of reagents, disks, stains, antisera and identification systems for positive and negative reactivity.
Syphilis Serology	
Concurrent control testing with a positive control of known reactivity and a negative control.	(D) Once each day, run two control materials of different concentrations.
Immunology (Diagnostic and General)	
Concurrent control testing with a positive control of known reactivity and a negative control.	(D) Once each day, run two control materials of different concentration.
Hematology	
Each eight hours of operation (for non-manual testing, excluding coagulation) use two levels of controls.	(D) Once each day, run two control materials of different concentrations.